



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: James J. BARRY, et al.

Appl'n No.: 09/842,833

Filing Date: April 27, 2001

For: METHOD AND SYSTEM FOR
DELIVERY OF COATED
IMPLANTS

Group Art Unit: 3738

Examiner: Alvin J. Stewart

Mail Stop AF

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

The above-identified application having been finally rejected in the Final Office Action mailed March 7, 2006, the undersigned respectfully submits this Pre-Appeal Brief Request for Review. No Amendments are being filed with this Request. A Notice of Appeal is concurrently submitted herewith.

Remarks/Arguments

Status of Claims

Claims 1 and 3-11 are currently pending in the application. Claims 4, 5 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 6,287,285 by Michal et al. ("Michal") in view of U.S. Pat. No. 6,153,252 by Hossainy et al. ("Hossainy") further in view of U.S. Pat. No. 6,306,144 by Sydney et al. ("Sydney").

Claim 4 is the subject of the appeal.

Examples of the Invention

Embodiments of the invention include methods and systems for delivering coated medical implants. These methods and systems may serve to reduce damage to the coating of medical implants during the storage and / or delivery of the implants. In one embodiment, the surface of a balloon catheter is coated in order to resist damaging the coating of a coated stent

carried on and delivered by the balloon. There are numerous other embodiments of the present invention.

Appeal of Claim 4

a. The Office Action Interprets The Same Elements of Michal as Disclosing More Than One Feature of Claim 4.

Claim 1, the independent claim from which claim 4 depends, recites a “first implant adhesion resistant treatment,” and a “first implant coating.” Claim 4 also recites “two coaxial sleeves.” The final Office action cites to the same attributes of Michal as disclosing all of these features.

The final Office action, asserts that the top coat (20) and the base coat (19), of Figure 2 of Michal, are the “first implant adhesion-resistant treatment,” and the “first implant coating,” of claim 1. *See* pg. 3, para. 3. On page 4 of the Office action, it equates the same two coatings (19 and 20) to the “two coaxial sleeves” recited in claim 4. The Office action explains that “[t]he Examiner interpreted the two coating[s] (19 & 20) as being the two coaxial sleeves.” *See* pg. 4,

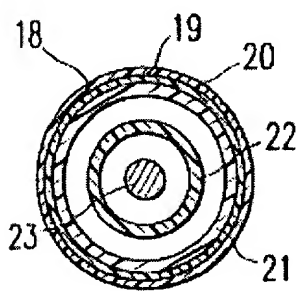


FIG. 2

para. 4. Thus, the Office action cites to top coat (20) as being the “first implant adhesion-resistant treatment” in independent claim 1, as well as one of the “coaxial sleeves” in dependent claim 4. Similarly, the Office action cites to base coat (19) as being the “first

implant adhesion-resistant treatment” in independent claim 1, as well as one of the “coaxial sleeves” in dependent claim 4.

To establish a *prima facie* case of obviousness, the prior art references must teach or suggest all the claim limitations. *See* MPEP § 2143.03. Since all the claim limitations are not taught or suggested in the cited references, a *prima facie* case of obviousness has not been shown. For at least this reason, claim 4 is patentable over the cited references.

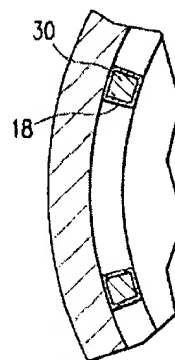


FIG. 12

b. The Office Action's Interpretation of "sleeves" is Erroneous.

The Office action argues that the term "sleeves" in claim 4, when interpreted broadly, could encompass a coating. This interpretation is erroneous and warrants withdrawal of the rejection.

During patent examination, claim terms are interpreted according to their ordinary and customary meaning given to the term by those of ordinary skill in the art. *See* MPEP § 904.01; § 2111.01. The ordinary and customary meaning of a term may be evidenced by the claims themselves, dictionaries and treatises, as well as the written description, drawings, and prosecution history. *See* MPEP § 2111.01 II.

Here, in the Remarks section in the Amendment After Final Rejection, filed May 23, 2006, the undersigned provided an example of the ordinary and customary meaning of the term "sleeve" by citing to the *American Heritage College Dictionary*, Third Edition, as well as Dictionary.com. Both references define "sleeve" as "a case into which an object or a device fits." The specification is not inconsistent with this meaning.

In making its rejection of claim 4, the Office action contends that a coating may be a sleeve. However, a coating is not a sleeve as it is not a case and is not sized to have a catheter fit within it or removed from it. Thus, claim 4 is also patentable because the Office action has adopted a new meaning for the word sleeve that has no support in the specification or its usual and customary definition.

CONCLUSION

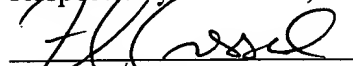
It is respectfully submitted that the rejection of claim 4 is improper and should be withdrawn and prosecution should be reopened.

The Office is authorized to charge any fees required under 37 C.F.R. § 1.16 or § 1.17 or credit any overpayments to Deposit Account No. 11-0600.

The Office is invited to contact the undersigned at 202-220-4200 to discuss any matter regarding this application.

Dated: August 9, 2006

Respectfully submitted,



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The Claims:

1. (Previously Presented) A coated implant delivery system comprising:
an implant delivery device with a first end, a second end, and an inner lumen,
the first end having a releasable implant retention region,
the releasable implant retention region having an accessible surface,
the accessible surface of the releasable implant retention region having a first
implant adhesion-resistant treatment; and
a releasable implant having a first implant coating,
the releasable implant releasably positioned in physical communication with the first
implant adhesion-resistant treatment on the surface of said releasable implant retention region,
the first implant coating facing the releasable implant retention region.
2. (Canceled)
3. (Previously Presented) The coated implant delivery system of claim 1 wherein the implant
delivery device is a balloon catheter.
4. (Previously Presented) The coated implant delivery system of claim 1 further comprising:

two coaxial sleeves positioned in physical communication with the releasable implant retention region,

wherein an exterior of the second end of the implant delivery device is treated with a second implant adhesion-resistant treatment.

5. (Previously Presented) The coated implant delivery system of claim 1 further comprising:
a conduit in fluid communication with the releasable implant retention region, wherein the accessible surface of the implant delivery device is treated with a second implant adhesion-resistant treatment.

6. (Previously Presented) The coated implant delivery system of claim 1 wherein the implant adhesion-resistant treatment includes a non-adhesive silicon coating.

7. (Previously Presented) The coated implant delivery system of claim 1 wherein the implant adhesion-resistant treatment includes a non-adhesive hydrophilic coating.

8. (Previously Presented) The coated implant delivery system of claim 1 wherein the implant adhesion-resistant treatment includes a non-adhesive hydrogel coating.

9. (Previously Presented) The coated implant delivery system of claim 1 wherein the implant adhesion-resistant treatment includes a non-adhesive carbowax coating.

10. (Previously Presented) The coated implant delivery system of claim 1 wherein the implant adhesion-resistant treatment includes a non-adhesive PEO coating.

11. (Original) The coated implant delivery system of claim 1 wherein the releasable implant is a balloon-expanding stent.